

## Vaccinologists are getting smarter

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I've been writing for 4 years now about the shift that will occur from injecting protein antigens or the message to make them, to something that is either inhaled or swallowed. Here we go:

(Reuters) - The U.S. Department of Health and Human Services (HHS) said on Thursday it will provide up to \$500 million for mid-stage trials evaluating vaccines administered as a nasal spray or pill to protect against symptomatic COVID-19. The funding is part of Project NextGen, a \$5 billion initiative led by the Biomedical Advanced Research and Development Authority (BARDA), to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection against COVID-19 infection. BARDA, which helps companies develop medical supplies to address public health threats, is a part of HHS. The project is awarding up to \$453 million to Vaxart for a study that will evaluate its oral COVID vaccine. The company's shares more than doubled to \$1.78 after market. It is also awarding privately held Castlevax and Cyanvac around \$34 million and \$40 million, respectively, to develop their intranasal vaccine candidates. Each trial will enroll 10,000 volunteers and compare the efficacy and safety of the investigational vaccines to FDA-licensed vaccines.

The reason for this inevitable shift to mucosal vaccines is because science has finally admitted that you cannot get mucosal protection against future infections by ignoring the mucosal barrier and injecting something into the body. When antigens come through the mucosal barrier naturally, mucosal IgA antibodies are secreted into the mucosa that will block future infections. Also, cytotoxic T-cells with memory will be just inside the mucosal barrier to destroy epithelial cells that display those antigens before the virus gets replicated and released, further protecting against future infections.

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It is important to understand that the pathogen, whatever it is, a virus, bacterium, fungus, spore, parasite, or man-mad bioweapon is NOT the antigen. The protein parts of them are the antigens. Your immune system can only recognize proteins or smaller protein parts called peptides. You have special immune cells called APCs or Antigen Presenting Cells that chop foreign invaders into all its protein parts and display them on their surfaces. T-helper cells are constantly looking at these displayed proteins and when they find one that is not self, a whole complicated series of events happens that builds many different antibodies and trains cytotoxic T-cells to keep you protected.

What these genius scientists haven't figured out yet is that to get fully protective and robust immunity, the immune system must experience the entire foreign invader, all protein parts of it, not just select pieces of it. So far, these investigational products are presenting select pieces of viruses, so when they get mutated as they most certainly will, the protection that was provided will be lost.

When a cell is naturally infected with the Sars-CoV-2 virus, all protein parts of it are broken into smaller pieces called peptides, and these are displayed on the surface of the cell on MHC-I sites. The entire spike protein is never displayed on these sites, only smaller pieces of it. This results in robust antibody production that can react to various parts of the spike protein so that when it mutates, the antibodies will still work. This doesn't happen when cells take in the manmade modified mRNA cleverly hidden in lipid nanoparticles. These cells will display the **entire spike protein** and it gets cleaved off and circulates in the bloodstream and interstitial fluids. This allows B-cells to take in the entire spike protein and build antibodies against the whole thing. When the spike protein changes, the antibodies are suboptimal and ineffective.

All three of these mucosal vaccines are going to end up creating suboptimal antibodies because they are still having the cell manufacture and display the entire spike protein through mRNA, but in a different way.

Vaxart is using the same method that the failed J&J adenoviral vector covid shot used. It's using the adenovirus type 5 virus, a DNA virus that has been altered by

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inserting into the adenovirus, the DNA that is complementary to the nucleotide sequence of the Sars-CoV-2 spike protein. The only difference is the route of infection. The J&J was an injected infection, whereas the swallowed Vaxart pill will allow the adenovirus to infect the epithelial cells of the gut lining. When the modified DNA of the adenovirus enters the cytoplasm, it is taken in by the nucleus. In the nucleus, the DNA is transcribed into messenger RNA that will leave the nucleus and be used by ribosomes to translate the mRNA into the spike protein. The spike protein gets released from the cell, enters the circulation, and allows B-cells to build suboptimal antibodies against the whole protein. Worse, that protein is biologically active, meaning that it will attach to other cellular receptors. It is not willingly taken in by the cell, it attaches to cellular receptors and just sits there. This further activates the immune system to destroy those cells, and if the tissue damage continues, the same pathologies that happened with the injectable products will occur.

The CastleVax and CyanVac inhalable products use RNA viruses instead of DNA viruses. CastleVax is using an attenuated Newcastle Disease Virus while CyanVac is using recombinant parainfluenza virus 5 (PIV5). Both altered viruses contain the nucleotide sequence for the spike protein. They also contain an RNA dependent RNA polymerase that will convert the inserted nucleotide sequence into messenger RNA that will be used by ribosomes to make the spike proteins. The nucleus of the infected cell is not involved. The spike proteins are manufactured and released by the cell, and here we go again with suboptimal antibodies and pathologies.

It's time for scientists to admit they can't outsmart the way God designed the immune system to react to infections and protect against future infections. It's also time for everyone to realize that all communicable diseases, even bird flu if it "jumps" into humans, are manageable with supportive care and should not be feared.

Thanks for reading, and thanks for staying smart.